UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,100	06/29/2007	Meiyu Geng	09548.1045USWO	7023

52835 7590 09/15/2011

HAMRE, SCHUMANN, MUELLER & LARSON, P.C.
P.O. BOX 2902
MINNEAPOLIS, MN 55402-0902

EXAMINER	
MAIER, LEIGH C	

ART UNIT	PAPER NUMBER
1623	

MAIL DATE	DELIVERY MODE
09/15/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/594,100	GENG ET AL.	
	Examiner	Art Unit	
	LEIGH MAIER	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 February 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *11-22* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☒ Claim(s) *11-17,19 and 20* is/are allowed.

7)☒ Claim(s) *18 and 22* is/are rejected.

8)☒ Claim(s) *21* is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/GB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 18, 2011 has been entered.

Claim 18 has been amended. Claims 21 and 22 are newly added. Claims 11-22 are pending.

Any objection or rejection not expressly repeated has been withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The declaration under 37 CFR 1.132 filed July 16, 2010 is not sufficient to overcome the rejection of claims 18 and 22 based upon 35 USC 112, 1st paragraph. The declaration is addressed below.

Claim Objections

Claim 22 is objected to because of the following informalities: The claim, in the last line, recites "legion" where "lesion" appears to be intended. Appropriate correction is required.

Claim Rejections - 35 USC § 112

Claims 18 and 22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling the use of the recited oligosaccharides in (1) the treatment of type 2 diabetes; (2) the treatment of type 1 diabetes in combination with insulin (but this particular method does not appear to be supported); or (3) the treatment of Alzheimer's disease (AD), does not reasonably provide enablement for the prevention of either type of diabetes or the prevention of AD or treatment for the full scope of oligosaccharides. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The claims are not particularly broad in scope and one of ordinary skill in the art would be expected to be a highly trained practitioner. However, the prevention of the recited diseases remains problematic and highly unpredictable.

The instant disclosure demonstrates that the 6-mer has blood glucose lowering capacity in mice having induced diabetes, similar to the effect of dimethyldiguanide (metformin). Davies et al (Diabetic Medicine, 2004) discusses the difficulties involved in the prevention of diabetes, including the use of pharmaceutical agents. See, particularly the text at pp 405-408 and Table 2. This reference reports spotty positive results using such agents. However, in general, the results are negative. Therefore, there is nothing to suggest that one of ordinary skill would have a reasonable expectation that an agent known to treat type 2 diabetes would also prevent it.

The prevention of type 1 diabetes is even more difficult particularly because it is more difficult to screen and select patients who are at increased risk. See discussion in Skyler et al (Diabetes Care, 2005). This reference finds that the administration of insulin, the standard

treatment of type 1 diabetes, does not delay the onset of the disease in relatives of known patients having the disease. There is no evidence that the use of the instant product would have any benefit in the prevention of type 1 diabetes. Further regarding treatment, as noted, insulin is the standard treatment for type 1 diabetes. While a combination of the instant product with insulin, as with metformin and insulin as described by Hamilton et al (Diabetes Care, 2003), might be beneficial to the treatment of type 1 diabetes, there is no evidence that this product would be beneficial to patients in the absence of exogenous insulin.

The prevention of AD is more challenging still. Doraiswamy et al (Exp. Opin. Pharmacother., 2006) discusses the difficulties as length. See particularly sections 2, 3 and 4.10. Although AD is an intensely studied disease, the actual cause remains a mystery, and many potential surrogate biological markers for prevention have not been validated. Prevention trials are expensive and take many years. See section 5.

In view of the foregoing difficulties associated with prevention of the recited diseases, one of ordinary skill would require undue experimentation to implement this method commensurate with its scope.

Applicant's arguments filed February 18, 2011 have been fully considered but they are not persuasive.

The declaration presents data showing inhibition of Applicant Aβ aggregation. Applicant further cites Selkoe (Trends in Cell Biology, 1998) to support the contention that "inhibiton of Aβ aggregation prevents initiation of AD." Yet with more than a decade of intensive research after Selkoe, actual prevention remains elusive. Regarding prevention, Marchesi (FASEB J., 2011) reviews at length the difficulties with prevention and the drawbacks of the amyloid

hypothesis in general. The reference states that prevention "is unrealistic at this stage of our knowledge, since we lack any clear insight as to when the disease first starts and how it develops to a full-blown clinical stage." It is also unknown if "blocking the production of Aβ or removing it from circulation will compromise normal brain functions." See page 11. The reference further states that, several years after Applicant's disclosure, it remains unknown "whether the presence of amyloid deposits in brains at any stage of the disease represents a consequence of the disease rather than its primary cause." Furthermore, "It remains an unproven assumption that amyloid deposits acting alone are the most important pathogenic agents." See page 6 at the paragraph bridging the columns.

With respect to type 2 diabetes, the declaration presents data demonstrating the inhibition of amylin aggregation. Applicant states that this aggregation if a hallmark of this disease. However, Applicant presents no evidence demonstrating that such inhibition is known to be useful in preventing it. Clark et al (Protein Rev., 2007) agrees that this aggregation is a feature of type 2 diabetes but goes onto at length the lack of specific knowledge regarding how relevant the fibrils and islet amyloidosis in diabetes initiation/pathology. The reference discusses the interest in developing inhibitors of islet amyloidosis, but states that they would be potential therapeutic agents, as "the evidence suggests that islet amyloidosis is not a precipitating factor for hyperglycemia in most patients but could result from complications of the disease." The reference further discusses the difficulty in experimentation to develop/assess such treatment, or even less likely, prevention. See entire reference, particularly sections 10.5.2 and 10.6.

Allowable Subject Matter

Claims 11-17, 19 and 20 are allowed for reasons of record. Claim 21 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Examiner's hours, phone & fax numbers

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (571) 272-0656. The examiner can normally be reached on Monday, Tuesday and Thursday 7:00 to 4:30 (ET). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Anna Jiang at (571) 272-0627, may be contacted. The fax number for Group 1600, Art Unit 1623 is (703) 872-9306.

Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished application is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

/Leigh C. Maier/
Primary Examiner
Art Unit 1623